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A Preliminary Investigation of a Relapse Prevention Mobile Application to Maintain Smoking Abstinence among Individuals with Posttraumatic Stress Disorder

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Abstract

Objectives—Smokers with posttraumatic stress disorder (PTSD) have increased difficulty achieving and maintaining abstinence. Contingency management approaches to smoking cessation interventions have demonstrated short-term efficacy, but are limited by high rates of relapse. The goal of this pilot study was to evaluate the usability and feasibility of a smartphone-based smoking cessation application (Stay Quit Coach) designed to prevent relapse among individuals with PTSD.

Methods—Smokers ($N = 11$) were randomized to 1) QUIT4EVER, an intervention combining mobile contingency management smoking cessation counseling and medications, and Stay Quit Coach or 2) a contact control condition that was identical to QUIT4EVER except Stay Quit Coach was not included. The primary outcome was prolonged smoking abstinence.

Results—Among those queried during the follow-up periods, average Stay Quit Coach helpfulness ratings were high and ranged from 7.25–10 on a 10-point Likert scale (with higher scores corresponding to greater helpfulness). The Stay Quit Coach was rated by participants as being most effective at helping to quit smoking, helping to remain quit, and providing support and relevant information about quitting. Among the 3 quitters in the QUIT4EVER group, all reported abstinence at 3 and 6 months; however, abstinence was only bioverified for one quitter at 6

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months. Among the 4 quitters in the contact control condition group, 3 reported abstinence at 3 and 6 months, but abstinence was not confirmed by bioverification.

Conclusions—Smokers with PTSD express interest in and helpfulness of Stay Quit Coach for remaining abstinent after a quit attempt. Combined use of mobile contingency management and Stay Quit Coach is a feasible and acceptable adjunctive smoking cessation treatment for reducing smoking among smokers with PTSD. Adequately powered clinical trials are needed to demonstrate the long-term efficacy of this combined approach to smoking cessation.

This study [Use of Technological Advances to Prevent Smoking Relapse among Smokers with PTSD (QUIT4EVER)] was registered on www.clinicaltrials.gov. clinicaltrials.gov identifier: NCT01990079.

Keywords

smoking cessation; tobacco; nicotine; cognitive-behavioral therapy (CBT); posttraumatic stress disorder (PTSD); contingency management; mobile health; public health

Introduction

Despite evidence that smokers with posttraumatic stress disorder (PTSD) want to quit (Kirby et al., 2008), they have poor quit rates, shorter time to post-quit lapse, and low 12-month smoking abstinence rates (Beckham, Calhoun, Dennis, Wilson, & Dedert, 2012; Fiore et al., 2000; Hapke et al., 2005; McFall et al., 2010). Thus, smokers with PTSD may require more intensive smoking cessation interventions, such as an integrated care model for smokers with PTSD with adjunctive treatments (e.g., contingency management, mobile technology approaches). Contingency management is a behavioral intervention that involves monetary compensation for verified abstinence and has been used to reduce drug use, including tobacco, in a wide range of populations (Knapp, Soares, Farrel, & Lima, 2007; Kollins, McClernon, & Van Voorhees, 2010; Lee & Rawson, 2008; Prendergast, Podus, Finney, Greenwell, & Roll, 2006; Roll, Higgins, Steingard, & McGinley, 1998; M. Stitzer & Petry, 2006; M. L. Stitzer et al., 2007; Tidey, O'Neill, & Higgins, 2002). While the short-term efficacy of contingency management for smoking cessation has been demonstrated, it appears that treatment effects may not last once incentives cease (Carroll & Onken, 2005; Ledgerwood, 2008; Petry, 2010; Prendergast et al., 2006). In order to address this concern, long-term efficacy of contingency management may be improved by adding relapse-prevention support.

This support may be effectively delivered through mobile phone applications (apps), which have been used increasingly to deliver behavioral health interventions. While apps show promise in treating substance use (Donker et al., 2013), many smoking cessation mobile apps do not adhere to clinical practice guidelines (Abroms, Westmaas, Bontemps-Jones, Ramani, & Mellerson, 2013). The Stay Quit Coach app – modeled after an evidence-based treatment for smokers with PTSD (McFall et al., 2010) – was designed to be a guideline-concordant aid to promote smoking abstinence (Hoffman, Kuhn, Wald, & Ruzek, 2013). Stay Quit Coach guides users in creating a tailored plan that takes into account their personal reasons for quitting. It provides information about smoking and quitting, interactive tools to

help users cope with urges to smoke, and motivational messages and support contacts to help users stay smoke-free (National Center for PTSD, 2016). The app's personalization and interactive nature make Stay Quit Coach an ideal adjunctive treatment for relapse prevention.

The goal of the current pilot study is to evaluate the usability and feasibility of Stay Quit Coach. The pilot intervention, QUIT4EVER, combined a mobile platform for contingency management, smoking cessation counseling, medication, and the Stay Quit Coach app. The aims of the pilot were to: 1) assess the impact of QUIT4EVER on medication adherence and 2) evaluate the overall helpfulness and acceptability of Stay Quit Coach.

Methods

Participants

A total of 11 adult smokers with PTSD were enrolled. Participants were screened prior to enrollment and were eligible if they: smoked 10 cigarettes a day; smoked 1 year; current PTSD based on the Clinician Administered PTSD Scale [CAPS; (Blake et al., 1990)]; ability to speak/write conversational English; between 18 and 70 years of age; and willing to quit smoking. Exclusion criteria included: myocardial infarction in the past 6 months; contraindication to nicotine replacement therapy (NRT) without medical clearance; use of and unwillingness to quit other tobacco products; current pregnancy; primary psychotic disorder or current manic episode as determined by the Structured Clinical Interview for the *Diagnostic and Statistical Manual of Mental Disorders* (First, Spitzer, Gibbon, & Williams, 1994); or current enrollment in another smoking cessation trial. Four people were excluded due to current drug use ($n = 2$), not meeting criteria for current PTSD ($n = 1$), and current psychosis ($n = 1$).

Procedures

The design was a two-arm, computer-based randomized clinical trial comparing QUIT4EVER to a Combined Contact Control. Medical evaluation and clearance to participate in the trial was provided by each participant's primary care provider (PCP) or (when the PCP could not be reached) the study physician. The study protocol was approved by the Duke University Institutional Review Board, and participants provided written informed consent prior to study entry.

In both conditions, participants received a mobile phone with the preinstalled mobile contingency management app, smoking cessation counseling, and smoking cessation medications. The mobile contingency management app enabled participants to receive monetary compensation for smoking abstinence based on two at least 8 hours apart daily carbon monoxide (CO) readings 6 parts per million (ppm), which were recorded with the provided mobile phone's video camera and uploaded to our lab's secure server to be watched for verification for 7 weeks. Participants could earn a maximum of \$530 for abstinence, with a previously reported average compensation level of \$300 (Carpenter et al., 2015b). Participants in this trial were 92% compliant with the mobile contingency management schedule with an average compensation level of \$292. For further information

on mobile contingency management methodology, see Hertzberg et al., 2013 and Carpenter et al., 2015.

Best practice techniques were used for smoking cessation counseling and medications (McFall et al., 2010). Smoking cessation counseling consisted of a participant workbook as well as four 20-minute best-practice cognitive behavioral therapy (CBT) for smoking cessation sessions (see Carpenter et al., 2015). NRT included the nicotine patch and one rescue method (e.g., gum, lozenge, or inhaler). Additionally, all participants (for whom it was not contraindicated) were prescribed bupropion, starting 2 weeks prior to the quit day at dosage level 150 mg once daily and then twice daily until the 3-month follow-up (Agboola, McNeill, Coleman, & Bee, 2010; Jorenby et al., 1999).

QUIT4EVER intervention condition—The Stay Quit Coach app was only preinstalled on the provided mobile phones of participants in the QUIT4EVER group. Stay Quit Coach is based on integrated care for smoking cessation, which is a treatment tailored for the specific needs of patients with chronic post-traumatic stress disorder (PTSD) and designed to be integrated into ongoing psychotherapy (McFall et al., 2010). The app was designed to help individuals who have quit smoking stay quit, and creates tailored plans that include users' personal reasons for quitting, interactive tools to help users cope with urges to smoke, motivational messages, support contacts to help users stay smoke free and how to address lapses. A more complete description can be found at http://www.ptsd.va.gov/professional/materials/apps/stayquit_coach_app_pro.asp and <https://itunes.apple.com/us/app/stay-quit-coach/id655892317?mt=8>. In order to integrate Stay Quit Coach into counseling sessions, counselors assisted participants in populating the app with personalized information during each counseling session. Participants were encouraged to use Stay Quit Coach between counseling sessions and during post-treatment.

Measures

Baseline measures included the CAPS, the Beck Depression Inventory [BDI; (Beck, Steer, & Brown, 1996)], the Fagerström (Heatherton, Kozlowski, Frecker, & Fagerström, 1991), the Questionnaire on Smoking Urges [QSU; (Tiffany & Drobes, 1991)], the Relapse Situation Efficacy Questionnaire [RSEQ; (Gwaltney, 2001)], and a smoking history questionnaire.

Process measures included adherence, self-efficacy, and evaluation of the Stay Quit Coach app. The Morisky Adherence Questionnaire (Morisky, Green, & Levine, 1986; Toll, McKee, Martin, Jatlow, & O'Malley, 2007) was administered at post-treatment. Scores on this previously-validated 8-item questionnaire could range from 0 to 7 (lower scores indicate better adherence) (Catz et al., 2011). In the QUIT4EVER group, participants also completed the Stay Quit Coach Evaluation, a self-report measure that probed how well Stay Quit Coach helped maintain abstinence (rated on a 10-point Likert scale with higher scores corresponding to greater helpfulness).

All smoking abstinence outcomes were bioverified by either a) expired air CO concentration 6 ppm and/or b) salivary cotinine < 10 ng/mL. Participants who lacked bioverification or failed to attend follow-up visits were considered non-abstinent. CO-bioverified early

abstinence outcome measures included 7-day point-prevalence abstinence at immediate post-treatment and at two weeks post-treatment. Cotinine-bioverified long-term abstinence outcomes included 3- and 6-month prolonged abstinence, assessed using the Timeline Follow-back Procedure (Sobell & Sobell, 1992). Participants met criteria for prolonged abstinence if they did *not*: smoke on 7 consecutive days, smoke at least once a week for any 2 consecutive weeks, use non-cigarette tobacco for 7 consecutive days, or use non-cigarette tobacco at least once a week for any 2 consecutive weeks (Hughes et al., 2003).

Results

Table 1 presents baseline demographic and clinical information. Most participants were African American, and on average participants had smoked for over 3 decades. Regarding participant retention throughout the small trial, 1 participant randomized to QUIT4EVER dropped out during treatment due to scheduling conflict, and the other 4 QUIT4EVER participants completed treatment and returned for 3- and 6-month follow-up. All participants randomized to the Combined Contact Control condition completed treatment, although 3 of the 6 Combined Contact Control participants were lost to contact at the 3- and 6-month follow-ups.

Regarding adherence to NRT and bupropion, participants in the Combined Contact Control group reported low scores (i.e., high adherence) on the Morisky Adherence Questionnaire ($M = 1.67$, $SD = 1.97$). Participants in the QUIT4EVER condition reported moderate adherence scores ($M = 3.5$, $SD = 3.51$).

Regarding compliance to using the Stay Quit Coach app, rates of use were generally high. At the 3-month follow-up, QUIT4EVER participants reported a variety of levels of Stay Quit Coach app use: two reported using it at least once per day; another participant reported using Stay Quit Coach at least once per week; and a fourth participant reported using it at least twice per month. At the 6-month follow-up period, Stay Quit Coach use was reported as at least once per day for one QUIT4EVER participant, several times per week for one participant, and at least twice per month for one participant.

Stay Quit Coach participant satisfaction evaluation yielded mostly positive results (Table 2). Average Stay Quit Coach helpfulness ratings ranged from 7.25–10 among those queried during the follow-up period. The Stay Quit Coach was rated by participants as being most effective at helping to quit smoking, helping to remain quit, and providing support and relevant information about quitting.

At immediate post-treatment, 60% (3 of 5) of the QUIT4EVER and 100% (6 of 6) of the Combined Contact Control participants achieved CO-bioverified point-prevalence abstinence. At 2 weeks post-treatment, 60% (3 of 5) of QUIT4EVER participants and 67% (4 of 6) of the Combined Contact Control participants achieved point-prevalence abstinence. Among quitters in the QUIT4EVER group, all three reported prolonged abstinence at 3 and 6 months; however, one refused to provide a cotinine sample for bioverification, one failed cotinine bioverification at 3 and 6 months, and the third failed cotinine bioverification at 3 months, but not 6 months. Among quitters in the Combined Contact Control group, three

self-reported prolonged abstinence at 3 months; one refused to provide a cotinine sample and the other two quitters failed cotinine bioverification.

Discussion

Feasibility was demonstrated in terms of the general randomized trial approach and of combined mobile contingency management and Stay Quit Coach app use for smoking cessation among smokers with PTSD, as measured by compliance and participant retention. The study population also showed a high level of acceptability and perceived usefulness of the Stay Quit Coach app. The results are consistent with previous contingency management trials that demonstrated high rates of quitting during the treatment period but high relapse rates following the removal of contingencies (Carroll & Onken, 2005; Ledgerwood, 2008; Petry, 2010; Prendergast et al., 2006). In this pilot, Stay Quit Coach appeared to help one participant reach abstinence between the 3- and 6-month follow-up periods by providing educational materials about the benefits of quitting smoking, risks of smoking, medication and nicotine replacement and their efficacy in preventing relapse. Stay Quit Coach also provided tools and activities for coping with urges to smoke as well as perspectives and coping tools for those who smoke after their quit date. Access to support contacts or hotlines for preventing relapse, motivational messages, benefits of staying quit, and reminders to take medications were also useful tools in Stay Quit Coach. Since dropout was low for the QUIT4EVER protocol, these results also provide further evidence that smokers with PTSD are willing to use mobile apps for smoking cessation and that they found Stay Quit Coach helpful and easy to use.

Overall, although Stay Quit Coach was generally rated as helpful, data suggested that more research is needed to refine the intervention. For example, use of this app may be altered by use on a personal phone, which could promote higher engagement with the app. With more naturalistic integration of Stay Quit Coach, perhaps use of the app would increase. Future treatment combining CBT and Stay Quit Coach might also benefit from more detailed integration of Stay Quit Coach in the integrated care for smoking cessation treatment sessions (e.g., relying more heavily on Stay Quit Coach instead of both the participant workbook and Stay Quit Coach) and strongly encouraging use of the app outside of sessions. Although we collected self-reported use, it would be helpful for future studies to capture objective app use as well. Based on relatively low self-rated helpfulness scores of certain app features, Stay Quit Coach may benefit from improving components for controlled breathing, trigger management, and motivational messages.

Further research is needed to determine whether Stay Quit Coach and other behavioral health mobile apps influence long-term abstinence in smokers with PTSD. We observed excellent immediate treatment response and acceptability of the Stay Quit Coach and mobile contingency management apps in both the QUIT4EVER and Combined Contact Control conditions, which is consistent with previous contingency management smoking cessation trials (Carpenter et al., 2015a; Hertzberg et al., 2013); however, only one ex-smoker in the QUIT4EVER treatment condition was abstinent at the end of treatment and 6-month follow-up, but not at the 3-month follow-up. To help increase prolonged abstinence, mobile contingency management could be offered over the first 3 months of the follow-up period or

the full 6-month follow-up period. In summary, aspects of the current study underscore the potential for behavioral mobile health apps to promote long-term abstinence in smokers with PTSD, with the caveat that relapse-prevention strategies must be further developed.

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Table 1

Demographic and smoking information on study participants

	QUIT4EVER (<i>n</i> = 5)	CCC (<i>n</i> = 6)
<u>Sociodemographic Variable</u>	<i>n</i>(%)	<i>n</i>(%)
Race		
Black or African-American	5(100%)	5(83%)
White	0(0%)	1(17%)
Gender		
Male	1(20%)	3(50%)
Female	4(80%)	3(50%)
Marital Status		
Married	0(0%)	1(17%)
Never Married	3(60%)	3(50%)
Separated/Divorced	2(40%)	2(33%)
Veteran	1(20%)	3(50%)
<u>Baseline Value</u>	<i>Mean (SD)</i>	<i>Mean (SD)</i>
Age (years)	53.2 (10.5)	54.3 (9.5)
Education (years)	14.6 (3.0)	13.2 (1.3)
Age of Smoking Onset (years)	18.4 (8.1)	21.2 (9.0)
Years Smoking	31.6 (9.8)	32.7 (9.8)
Cigarettes/day	17.0 (8.2)	18.2 (11.3)
Expired Carbon Monoxide (CO)	15.8 (8.4)	16.2 (5.8)
# of Past Quit Attempts > 24 hrs	2.4 (2.7)	7.3 (11.2)
BDI	22.4 (6.1)	24.8 (8.2)
CAPS Total Score	40.2 (14.1)	42.2 (2.5)
Fagerström	7.2 (0.8)	6.5 (0.8)
QSU		
Factor 1	6.1 (1.1)	5.6 (0.7)
Factor 2	6.2 (1.1)	4.4 (1.3)
RSEQ	120.7 (31.9)	148.0 (32.2)

Abbreviations: CCC: Combine Contact Control; CO: Carbon Monoxide; BDI: Beck Depression Inventory; CAPS: Clinician Administered PTSD Scale for the Diagnostic and Statistical Manual of Mental Disorders; QSU: Questionnaire of Smoking Urges; RSEQ: Relapse Situation Efficacy Questionnaire

Table 2

Stay Quit Coach (SQC) evaluation results at 3- and 6-month follow-ups

Question	3-month follow-up (<i>n</i> = 4)			6-month follow-up (<i>n</i> = 3)		
	(<i>n</i>)	Mean (<i>SD</i>)	Range	(<i>n</i>)	Mean (<i>SD</i>)	Range
How helpful was SQC?	4	8.0 (2.2)	5–10	3	9.7 (0.6)	9–10
How helpful was “My Reasons” section?	4	7.8 (2.1)	5–10	3	9.7 (0.6)	9–10
How helpful was “Risks and Benefits” section?	3 ^a	10.0 (0.0)	10	3	9.3 (1.2)	8–10
How helpful was “Controlled Breathing” tool?	2 ^b	7.5 (3.5)	5–10	2 ^d	10.0 (0.0)	10
How helpful was “Manage Smoking Triggers” tool?	4	7.3 (2.2)	5–10	2 ^d	10.0 (0.0)	10
How helpful was “Motivational Messages” tool?	4	7.3 (3.6)	2–10	3	9.7 (0.6)	9–10
How helpful was “Medications” section?	2 ^b	7.5 (3.5)	5–10	2 ^d	9.0 (1.4)	8–10
How helpful was “Learn” tool?	3 ^a	8.0 (2.7)	5–10	2 ^d	9.0 (1.4)	8–10
How helpful was “My Progress” section?	3 ^a	10.0 (0.0)	10	2 ^d	10.0 (0.0)	10
How helpful was “I Smoked” section?	2 ^b	7.5 (3.5)	5–10	3	10.0 (0.0)	10
How helpful was “Get Support” section?	2 ^b	9.0 (1.4)	8–10	2 ^d	10.0 (0.0)	10
Was the app’s information relevant?	4	9.3 (1.5)	7–10	3	10.0 (0.0)	10
How helpful was SQC in helping to quit?	4	8.5 (2.4)	5–10	3	10.0 (0.0)	10
How helpful was SQC in helping to remain quit?	4	8.3 (2.4)	5–10	3	10.0 (0.0)	10
If relapse, how helpful was SQC in helping to quit again?	3 ^c	7.7 (4.0)	3–10	0 ^e		
How useful would SQC be to other people?	4	9.5 (1.0)	8–10	3	10.0 (0.0)	10

^a 3 QUIT4EVER participants reported using this section of the app at the 3-month follow-up^b 2 QUIT4EVER participants reported using this section of the app at the 3-month follow-up^c 3 QUIT4EVER participants reported a relapse and used this section of the app at the 3-month follow-up^d 2 QUIT4EVER participants reported using this section of the app at the 6-month follow-up^e 0 QUIT4EVER participants reported relapse and used this section of the app at the 6-month follow-up